IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MARGARET SCHMERLING and MORTON SCHMERLING	:	**CIVIL ACTION**
v.	:	
DANEK MEDICAL, INC., et al.	:	**NO. 96-2749**

M E M O R A N D U M

WALDMAN, J. **September 9, 1999**

I. Introduction

This is one of more than 2,000 personal injury cases filed nationwide in which plaintiffs have alleged that they were injured by the implantation of orthopedic bone screws in the pedicles of their spines.[1] Jurisdiction is based on diversity of citizenship pursuant to 28 U.S.C. § 1332.

This case was one of those consolidated by the Multidistrict Litigation Panel and transferred to the Honorable Louis Bechtle for pretrial management. The cases were then remanded to the transferor courts for adjudication of dispositive and other case-specific motions.

Presently before the court are the motions of defendants Sofamor Danek Group, Inc., Sofamor, S.N.C., Sofamor, Inc. and Danek Medical, Inc. (collectively "Sofamor/Danek") and

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[1] Counsel filed virtually identical complaints naming as defendants every manufacturer and distributor in the field, although it clearly appears that not all such defendants could have manufactured or marketed all of the devices at issue in each case.

Youngwood Medical Specialties, Inc. ("Youngwood") for summary judgment.[2]

II. Legal Standard

In considering a motion for summary judgment, a court determines whether "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986); Arnold Pontiac-GMC, Inc. v. General Motors Corp., 786 F.2d 564, 568 (3d Cir. 1986). Only facts that may affect the outcome of a case are "material." Anderson, 477 U.S. at 248. All reasonable inferences from the record are drawn in favor of the non-movant. Id. at 256.

Although the movant has the initial burden of demonstrating the absence of genuine issues of material fact, the non-movant must then establish the existence of each element on which it bears the burden of proof. J.F. Feeser, Inc. v. Serv-A-Portion, Inc., 909 F.2d 1524, 1531 (3d Cir. 1990) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)), cert. denied, 499 U.S. 921 (1991). A plaintiff cannot avert summary judgment with speculation or conclusory allegations, but rather

[2]The claims against all defendants except the five movants have now been dismissed upon stipulations of counsel and corresponding court orders entered herein.

must present evidence from which a jury could reasonably find in his favor. Ridgewood Bd. of Educ. v. N.E. for M.E., 172 F.3d 238, 252 (3d Cir. 1999).

III. Facts

From the evidence of record, as uncontroverted or otherwise in the light most favorable to plaintiffs, the pertinent facts are as follow.

Plaintiff Margaret Schmerling was diagnosed with scoliosis, or curvature of the spine, in 1967 or 1968 when she was eleven years old. She then underwent spinal fusion surgery during which a device called a Harrington rod was implanted in her spine. The Harrington rod remained in her spine for about five years. It was then removed without serious complications. She later underwent two subsequent back surgeries to remove residual tissue which continued to cause her irritation.

In 1989, after Mrs. Schmerling gave birth to her third child, she began to experience numbness in her left leg and pain in her left foot. She consulted with Richard Balderston, M.D., an orthopedic surgeon, who diagnosed her as having an increased lower back curve and disc abnormalities. On November 19, 1989, she underwent spinal fusion surgery at Pennsylvania Hospital in Philadelphia during which Dr. Balderston implanted in her spine components of a pedicle screw fixation system known as the Cotrel-Dubousset (C-D) system. The C-D system was designed,

manufactured and marketed by Sofamor/Danek and distributed by Youngwood.

The C-D system consists of rods, screws, hooks and other components. The various components come in an assortment of sizes. The individual surgeon selects components to fashion a fixation device appropriate to a particular patient based on the patient's size and condition. During spinal fusion surgery, bone graft material obtained from the patient's hip or from a "bone bank" is used to fuse the patient's vertebrae. The purpose of fixation systems such as the C-D system is to immobilize the spinal segments which are to be fused during the healing process.

During the 1989 surgery, Dr. Balderston implanted in Ms. Schmerling's spine C-D system components including hooks and a device known as a C-D rod. He did not, however, use the allegedly defective and illegally marketed bone screws which are the basis for this mass litigation.

Following this surgery, Mrs. Schmerling's leg pain subsided for about a year. Near the end of 1990, the pain returned. Mrs. Schmerling also began to experience pain in her hip. In September 1992, she underwent another surgery during which more of her spine was fused, the previously implanted C-D components were explanted and new C-D instrumentation implanted. The newly implanted C-D components included hooks and C-D rods,

although again none of the allegedly defective and illegally marketed bone screws.

Neither the 1989 nor 1992 surgeries fully relieved Mrs. Schmerling's pain. On February 7, 1994, she underwent her fourth spinal fusion surgery, the third in five years. As with the previous two surgeries, Dr. Balderston performed this procedure at Pennsylvania Hospital. During this surgery, Dr. Balderston performed an anterior-posterior spinal fusion, explanted the C-D instrumentation from the 1992 surgery and implanted new C-D components. The instruments implanted in her spine on this occasion included the alleged defective and illegally marketed bone screws which form the basis of this mass tort litigation.[3]

Following the February 1994 surgery, Mrs. Schmerling suffered several episodes of bladder incontinence. She continued to experience occasional leakage until at least 1997. She continues to experience debilitating back pain and pain in her left leg which radiates into her left foot.

Mrs. Schmerling, as all the other plaintiffs, has asserted state law claims for fraudulent misrepresentation, civil

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[3] Thus, the only C-D instrumentation at issue in this case are the C-D components implanted during Mrs. Schmerling's February 1994 surgery. See Second Amended Complaint, § II (amending complaint and first amended complaint by "substitut[ing]" allegation challenging C-D instrumentation implanted in Mrs. Schmerling's spine on February 7, 1994 in place of allegation in complaint and first amended complaint challenging C-D instrumentation implanted in Mrs. Schmerling's spine on November 19, 1989).

conspiracy, concert of action, fraudulent marketing and promotion, negligent misrepresentation, strict liability, liability per se, negligence and breach of implied warranty of merchantability. Mr. Schmerling has asserted a claim for loss of consortium.

Plaintiffs' fraudulent misrepresentation claim was predicated on the theory that several of the defendants, including Sofamor/Danek, defrauded the Food and Drug Administration (FDA) into permitting them to market the component parts of the C-D system, including the pedicle screws, as devices for implementation into long bones when defendants actually intended to market and did market the pedicle screws as part of a fixation system for use in spinal fixation surgery, which the FDA had not allowed. Judge Bechtle dismissed "all fraud on the FDA . . . claims contained in any pleading" in the consolidated litigation. On appeal, the Third Circuit held that the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., as amended by the Medical Device Amendments of 1976 (MDA), 21 U.S.C. §§ 360c-360k, did not preempt applicable state-law causes of action based on alleged fraudulent misrepresentations made to the FDA. See In Re Orthopedic Bone Screw Products Liability Litig., 159 F.3d 817, 828-29 (3d Cir. 1998). The Court did not hold, however, that any plaintiff had stated a claim upon which relief

could be granted for fraudulent misrepresentation under applicable state law. Id. at 829.

IV. Discussion

As all parties rely upon and assume the applicability of Pennsylvania substantive law, the court does so as well. See Neely v. Club Med Management Svces., 63 F.3d 166, 180 & n.10 (3d Cir. 1995); Mellon Bank, N.A. v. Aetna Business Credit, Inc., 619 F.2d 1001, 1005 n.1 (3d Cir. 1980). In any event, under the law of Pennsylvania or New Jersey, the state where plaintiffs reside and the only other state with any discernible interest, proof of causation is a necessary element for each of plaintiffs' claims. See, e.g., Mellon v. Barre-National Drug Co., 636 A.2d 187, 191 (Pa. Super. 1993) (products liability and negligence actions), appeal denied, 648 A.2d 789 (Pa. 1994); Redland Soccer Club v. Dep't of the Army, 55 F.3d 827, 851 n.15 (3d Cir. 1995) (negligence per se), cert. denied, 516 U.S. 1071 (1996); Petrucelli v. Bohringer & Ratzinger GMBH, 46 F.3d 1298, 1309 (3d Cir. 1995) (negligence, strict products liability, misrepresentation); Cruz-Mendez v. ISU/Insurance Services of San Francisco, 722 A.2d 515, 524 (N.J. 1999) (strict products liability); Fedorczyk v. Caribbean Cruise Lines, Ltd., 82 F.3d 69, 74 (3d Cir. 1996) (negligence) (applying New Jersey law); Cordy v. Sherwin Williams Co., 975 F. Supp. 639, 646 (D.N.J. 1997) (negligence per se); First Valley Leasing Inc. v. Goushy,

795 F. Supp. 693, 701 (D.N.J. 1992) (fraudulent misrepresentation).

To withstand summary judgment, plaintiffs must thus produce sufficient evidence from which a reasonable jury could find that the C-D instrumentation with bone screws utilized in the 1994 surgery caused Mrs. Schmerling's injuries.

To demonstrate causation, plaintiffs rely on a three-and-a-half page expert report of Dr. James Woessner. Dr. Woessner is a physiatrist, that is, a specialist in physical or "rehabilitation medicine." See Watts v. Organogenesis, Inc., 30 F. Supp. 2d 101, 107 (D. Mass. 1998); Goldstein v. United States, 9 F. Supp. 2d 175, 183 (E.D.N.Y. 1998). He received a bachelor of science degree in agriculture from Cornell University in 1971, a master of arts degree in biology and a Ph.D. in marine biology from the University of California-Santa Barbara in 1978 and 1981 respectively. He received his M.D. from the University of Miami, Florida, in 1987 through that university's "Ph.D. to M.D." program.

Dr. Woessner lists his "practice interests and skills" as "spinal cord injury," "impairment ratings," "functional capacity evaluations," "comprehensive pain management," "electroceuticals/pharmaceuticals," "work injury/sports injury," "head trauma/brain injury," "independent medical evaluations," "electrodiagnostics," "diagnostic ultrasound," "medico-legal

reviews" and "life care planning." It is uncontroverted that Dr. Woessner has no experience or training in the field of spinal surgery or the use of implanted hardware in the spine.

Dr. Woessner has never examined, interviewed or even met with Mrs. Schmerling. Indeed, Dr. Woessner uses male pronouns in referring to Mrs. Schmerling in several places in his report.

Dr. Woessner prepared his report based on medical and operative records provided by Dr. Balderston and certain medical records provided by Doctors Jeffrey Spivak, Prodromos Ververeli, David Lee, Randal Betz, as well as other unspecified medical reports. Dr. Spivak assisted Dr. Balderston during the 1992 surgery and apparently reviewed pertinent imaging reports before the operation. Dr. Betz is affiliated with Temple University Hospital and was consulted by Mrs. Schmerling for treatment or diagnostic purposes in 1995. He also found reviewing Mrs. Schmerling's x-rays germane to evaluating her condition. Dr. Lee is a neurologist to whom Mrs. Schmerling was referred for consultation in December 1996. He examined her and considered it appropriate to perform his own electromyelogram (EMG) test although he was familiar with the results of Mrs. Schmerling's prior EMGs. Dr. Ververeli's identity is not readily apparent from the record. It is uncontroverted that none of the

records or reports reviewed by Dr. Woessner included x-ray or other imaging studies of Mrs. Schmerling.

Dr. Woessner's report does not explain the basis for his conclusions. It merely summarizes portions of medical reports which Dr. Woessner read and states that:

> [b]ased on these findings, I have the following opinions:
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> There is a reasonable degree of medical certainty that the instrumentation not only did not correct the pathology that caused the original pain and disability, but also that the whole process of putting the instrumentation into her back, the tissue consequences of the dysfunctional hardware, and taking the instrumentation out of her back have also resulted in much tissue disruption and scarring in her back. Any remaining hardware and the abundant resultant scar tissue are very likely rubbing against nerve endings in many tissues in the area of the original injury and these subsequent surgical procedures, and are understandably causing nerve impingement, thus, pain and dysfunction. Pain, in and of itself, is well–known to cause disability. The instability is reestablished and the pain and disability have not improved, leaving the patient in a chronically deteriorated state. This case is a clear example of failure of non-FDA approved hardware.

Dr. Woessner's report does not explain what was "dysfunctional" about the C-D system or why he concluded it had "failed."

Mrs. Schmerling has been plagued with back problems since the age of 11. She has undergone at least six prior back surgeries. Four of these involved spinal fusion in which metal instruments were implanted in her spine. Three of these did not

involve use of the allegedly defective and illegally marketed pedicle bone screws and one involved no C-D system components. Yet, Dr. Woessner does not attempt to rule out alternate causes for her symptoms including prior spinal surgeries involving C-D components without bone screws or involving no C-D instrumentation, the placement of the bone screws, the technique of Dr. Balderston or the surgeons who performed the Harrington rod implantation and subsequent tissue removal surgeries, or the natural deterioration of the physical conditions which induced Mrs. Schmerling to undergo repeated spinal fusion surgeries to begin with. Dr. Woessner does not distinguish between the "instrumentation" or "hardware" implanted in Mrs. Schmerling's spine which included pedicle screws and that which did not.

Defendants have submitted an affidavit and expert report of John Hall, M.D. Dr. Hall has been a professor of orthopedic surgery at Harvard Medical School since 1971. He specializes in childhood spinal diseases, including scoliosis. Dr. Hall opined that "no reasonable physician would refer a patient with a complex spinal problem, such as Mrs. Schmerling had, to a physician with Dr. Woessner's qualifications to diagnose the cause of her continuing problems or to determine whether implanted hardware is painful [and that a]t most, Dr. Woessner might be qualified to provide some form of

rehabilitation treatment on the recommendation of a spine specialist."

Dr. Hall also notes Dr. Woessner's obvious lack of familiarity with the purpose of the C-D system which, with or without bone screws, was not intended to "correct the pathology that caused [Mrs. Schmerling's] original pain and disability" but rather to provide temporary support and to align and immobilize affected vertebrae while transplanted bone material gains strength and solidifies.

Dr. Woessner's proffered testimony is based upon claimed technical or specialized knowledge. Fed. R. Evid. 702 provides that:

> [i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Consistent with Fed. R. Evid. 104(a), the court must initially determine the qualifications of a proffered expert and the admissibility of his testimony under Rule 702. See Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 592 & n.10 (1993). The court is required to act as a gatekeeper to ensure that any expert testimony "is not only relevant, but [also] reliable." Kumho Tire Co., Ltd. v. Carmichael, 119 S. Ct. 1167, 1174 (1999) ("gatekeeping" requirement "applies to all expert

testimony"). The purpose of the gatekeeping function is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Id. at 1176.

To be admissible, proffered expert testimony must be based "on a reliable and scientifically valid methodology that fits with the facts of a case." Heller v. Shaw Industries, Inc., 167 F.3d 146, 152 (3d Cir. 1999). Among the guideposts the court may consider are whether the proffered expert's methodology has been tested if capable of testing; whether the technique has been subjected to peer review and publication; the known or potential rate of error of the methodology; and, whether the technique has been generally accepted in the proper scientific community. See Daubert, 509 U.S. 593-94; Heller, 167 F.3d at 152. Additional factors the court may consider are the existence and maintenance of standards controlling the technique's operation; the relationship of the technique to methods which have been established to be reliable; the expert witness's qualifications; and, the nonjudicial uses to which the method has been put. Id.; In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 n.8 (3d Cir. 1994), cert. denied sub nom General Electric Co. v. Ingram, 513 U.S. 1190 (1995).

The court has "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." Kumho Tire Co., 119 S. Ct. at 1176. The court's discretion in choosing the manner of testing expert reliability, however, "is not discretion to abandon the gatekeeping function." Id. at 1179 (Scalia, J., concurring). Moreover, even if expert testimony is admissible, summary judgment may still be appropriate if the non-movant has failed to present sufficient evidence to create a triable issue of fact. See Daubert, 509 U.S. at 596; Heller, 167 F.3d at 152.

As the proponent, plaintiffs bear the burden of showing that Dr. Woessner is qualified to render an expert opinion, that his opinion is reliable and that it would assist the trier of fact in resolving a disputed issue of material fact, i.e., causation. See, e.g., Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir.), cert. denied, 516 U.S. 869 (1995); Olinger v. United States Golf Ass'n, --- F. Supp. 2d ---, 1999 WL 410121, *2 (N.D. Ind. May 11, 1999); In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1244 (D. Colo. 1998).

Plaintiffs apparently misperceive who is required to prove what when a defendant in a civil case files a motion for summary judgment. Contrary to plaintiffs' suggestion, defendants were not required to come forward with "scientific evidence" negating plaintiffs' claims. They are entitled to point out

deficiencies in plaintiffs' proof. See, e.g., Celotex Corp., 417 U.S. at 325 ("the burden on the moving party may be discharged by 'showing' -- that is, pointing out to the district court -- that there is an absence of evidence to support the nonmoving party's case"); Riley v. Newton, 94 F.3d 632, (11th Cir. 1996), cert. denied, 519 U.S. 1114 (1997).

Plaintiffs were required to show that a reasonable jury could find in their favor on each issue on which they would bear the burden of proof at trial, including medical causation. See Celotex Corp., 417 U.S. at 322-23; Estate of Zimmerman v. Southeastern Pennsylvania Transp. Authority, 168 F.3d 680, 684 (3d Cir. 1999) (failure of plaintiffs in personal injury case to establish triable issue of fact on any element on which they would bear burden of proof at trial, including causation, is grounds for summary judgment). Indeed, when a claimant produces no competent evidence in support of an element he would be required to prove at trial, summary judgment is required. See Celotex Corp., 417 U.S. at 322-23 ("Rule 56(c) mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial"); Estate of Zimmerman, 168 F.3d at 684; Grunseth v. Marriott Corp., 872 F. Supp. 1069, 1072 (D.D.C. 1995), aff'd, 79 F.3d 169 (D.C. Cir. 1996); Schwartz v. Hospital

of University of Pennsylvania, 1993 WL 153810, *6 (E.D. Pa. May 6, 1993). Further, as noted, defendants did present the report and averments of a professor of orthopedic surgery and expert in spinal disease which challenged Dr. Woessner's qualifications and capability accurately to discern the cause of Mrs. Schmerling's symptoms and the methods he used in reaching his conclusion.

Plaintiffs' reliance on Petruzzi's IGA Supermarkets, Inc. v. Darling Delaware Co., 998 F.2d 1224 (3d Cir.), cert. denied sub nom Moyer Packing Co. v. Petruzzi's IGA Supermarkets, Inc., 510 U.S. 994 (1993) and United States v. Velasquez, 64 F.3d 844 (3d Cir. 1995) is totally misplaced. The former was an antitrust case in which the qualifications of plaintiff's expert economic witnesses were "unchallenged," in which they utilized reliable methods based on reasoning accepted in the published literature which produce reliable results if done properly and in which defendants failed to show any flaws in the experts' study. See Petruzzi's IGA Supermarkets, 998 F.2d at 1238. The Court merely concluded that in such circumstances it could not determine that the testimony was unhelpful "in the absence of countervailing evidence or persuasive argument." Id. Velasquez was a criminal case in which the court had held handwriting analysis sufficiently reliable to be the subject of expert testimony by a government handwriting expert who inculpated the defendant but then excluded the testimony of an appropriately

qualified defense expert critic of handwriting analysis whose proffered testimony met the reliability requirements of Rule 702. See Velasquez, 64 F.3d at 851.

Many courts in these bone screw cases have found that similar proffered expert testimony failed to create a triable issue of fact as to whether the allegedly defective and illegally marketed bone screws actually caused the plaintiffs' injuries. See Valente v. Sofamor, S.N.C., --- F. Supp. 2d. ---, 1999 WL 259494, *7-*8 (E.D. Wis. Apr. 29, 1999) (granting summary judgment after finding no competent evidence of causation where plaintiff's expert gave conclusory opinions, failed to identify a defect in the design or manufacture of the device and failed to perform differential diagnosis which is "antithetical to the scientific method"); Coleman v. Danek Medical, Inc., 43 F. Supp. 2d 637, 650 (S.D. Miss. 1999) (no competent evidence of causation where plaintiff's expert, except for conclusory assertions, failed to identify causal nexus between Danek's product and harm to plaintiff since failure to achieve solid fusion, increased pain and nerve damage are possible with fusion surgery involving no instrumentation or alternative instrumentation); Driggers v. Sofamor, S.N.C., 44 F. Supp. 2d 760, 765 (M.D.N.C. 1998) (granting summary judgment in case involving C-D system upon finding no competent evidence of causation where plaintiffs' expert failed to rule out other causes of plaintiff's pain);

O'Brien v. Sofamar, S.N.C., 1999 WL 239414, *4-*6 (E.D. Pa. Mar. 30, 1999) (granting summary judgment in case involving C-D system after finding proffered expert, a neurologist who never performed surgery and had no training or education in instrumented spinal fusion, was not qualified to render an expert opinion and even if so qualified, his testimony was unreliable in the absence of evidence of methodology employed and of evidence that expert performed a differential diagnosis and considered alternative explanations for plaintiff's worsened condition); Burton v. Danek Medical, Inc., 1999 WL 118020, *4 (E.D. Pa. Mar. 1, 1999) (excluding expert report and granting summary judgment where proffered expert was unfamiliar with the techniques of spinal fusion surgery and had no expertise with devices used in such surgery, performed no research other than reading articles provided by plaintiffs' counsel, did not examine plaintiff, did not perform differential diagnosis and did not disclose methodology he used); Leigh v. Danek Medical, Inc., 1998 WL 1041329, *4 (N.D. Tex. Dec. 14, 1998) (no competent evidence of causation where plaintiffs' expert failed to provide differential diagnosis, had not reviewed plaintiff's imaging studies, never examined or spoke with plaintiff and made no attempt to rule out other causes of pain including prior surgeries); Conger v. Danek Medical, Inc., 1998 WL 1041331, *5-*6 (N.D. Tex. Dec. 14, 1998) (striking expert reports and granting summary judgment where

plaintiff's proffered experts had never used spinal fixation devices, were not experts in field of spinal fusion surgery, had never met plaintiff, had not attempted to rule out other possible causes of pain and had failed to review all of plaintiff's x-rays, CAT and MRI scans); Love v. Danek Medical, Inc., 1998 WL 1048241, *2 (W.D. Ky. Nov. 25, 1998) (no competent evidence of causation where plaintiff's expert purportedly relied on plaintiff's medical records but failed to explain his reasoning and offered no facts to support his conclusion); Baker v. Danek Medical, 35 F. Supp. 2d 875, 880 (N.D. Fla. 1998) (plaintiff's expert's conclusion that implanted device caused symptoms because plaintiff suffered pseudoarthrosis after implantation and because pain diminished after explanation provided only "circular and speculative" support for causation insufficient to survive summary judgment); Smith v. Sofamor, S.N.C., 21 F. Supp. 2d 918, 921-23 (W.D. Wis. 1998) (granting summary judgment upon finding no competent evidence of causation). See also Jobe v. Sofamor, S.N.C., 1998 WL 1048208, *1 (D. Ariz. Sept. 4, 1998) (finding almost identical report of Dr. Woessner "woefully inadequate").

In a footnote, plaintiffs seek to bolster their position by suggesting that causation may otherwise be established by the report of Dr. Harold Alexander, a Ph.D. in applied mechanics. Plaintiffs rely on Judge Bechtle's Pretrial Order 725 in In re Orthopedic Bone Screw Litig., No. MDL 1014,

1997 WL 39583 (E.D. Pa. Jan. 23, 1997) for this proposition. Their reliance is misplaced. The report of Dr. Alexander on which plaintiffs rely is a generic critique of spine fixation devices which was submitted in virtually all of the bone screw cases. It does not mention any of the moving defendants in this case or any of their products and does not address plaintiff or how any C-D instrumentation, much less bone screws implanted in 1994, caused her symptoms. Judge Bechtle found that Dr. Alexander was qualified to offer expert testimony in the field of biomechanics or bioengineering, but was not qualified to give testimony requiring expertise in any other field including "clinical complications of pedicle fixation." See 1997 WL 39583, *2. See also Baker, 35 F. Supp. 2d at 881 (finding Dr. Alexander's report did not create a triable issue of fact); O'Brien, 1999 WL 239414, *2 n.4 ("Dr. Alexander cannot testify that [the C-D system] caused [plaintiff's] medical condition to worsen").

The court has serious doubts about the qualifications of Dr. Woessner, who is not an expert in spinal surgery or fixation devices, to render an expert opinion as to the origin of symptoms of a patient with a long history of serious back problems and surgeries, including multiple surgeries in which artificial instruments were implanted. The court has no doubt as to the unreliability of his opinion.

Dr. Woessner never examined Mrs. Schmerling or spoke with her or any physician who treated her. He did not review x-ray or other imaging studies of Mrs. Schmerling. Plaintiffs have made no showing that Dr. Woessner employed an acceptable method for determining the cause of a spinal surgery patient's symptoms. Indeed, plaintiffs have made no showing which would controvert Dr. Hall's averment that Dr. Woessner's conclusions and the method by which he reached them "must be considered well outside the range of reasonable medical decision-making."

Dr. Woessner fails to distinguish between the "instrumentation" or "hardware" which contained pedicle bone screws which is the subject of this action and the surgeries in which no bone screws were implanted. Insofar as Dr. Woessner concludes that the instrumentation placed in Mrs. Schmerling's back during the 1994 surgery caused her symptoms, this conclusion is not shared by her treating physicians who have found it quite difficult to narrow the causes of her symptoms given her medical history.

Dr. Woessner failed to perform anything remotely resembling a differential diagnosis to rule out other possible causes of the symptoms complained of. The failure of a proffered medical expert to explain why he concluded that other identified plausible other causes for a patient's symptoms are not the sole causes of those symptoms alone warrants a determination that the

expert's methodology is unreliable. See Heller, 167 F.3d at 156; In re Paoli R.R. Yard PCB Litig., 35 F.3d at 759 n.27.

Even assuming that Dr. Woessner is qualified to offer an opinion on the cause of Mrs. Schmerling's symptoms, there has been no showing from which the court could conscientiously find that his conclusions in this case are reliable. As Judge Bechtle previously concluded, Dr. Alexander cannot testify regarding clinical complications of bone screw surgery. He certainly cannot testify that any such complications are the cause of Mrs. Schmerling's symptoms.

Plaintiffs have thus failed to offer any competent evidence that any C-D instrumentation, let alone the C-D instrumentation including bone screws implanted in Mrs. Schmerling's spine on February 7, 1994, actually caused her symptoms. The complete failure of proof as to this essential element of all of her claims mandates the entry of summary judgment. See Celotex Corp., 417 U.S. at 322-23. See also Heller, 167 F.3d at 165 (summary judgment appropriate in absence of evidence of causation after expert testimony properly excluded).

Mr. Schmerling's loss of consortium claim is derivative of Mrs. Schmerling's claims. See Darr Construction Co. v. Workmen’s Compensation Appeal Board, 715 A.2d 1075, 1080 (Pa. 1998). Thus, defendants are entitled to summary judgment on this

claim as well. See Wakschul v. City of Philadelphia, 998 F. Supp. 585, 590 (E.D. Pa. 1998).

V. Conclusion

That claims are asserted en masse cannot excuse the plaintiffs from producing competent evidence sufficient to sustain the elements of each plaintiff's claims, including causation. The court has no doubt that Mrs. Schmerling genuinely suffers from back problems dating back to her childhood. She has not, however, produced sufficient competent evidence from which one reasonably can conclude that the conduct of these defendants caused the symptoms attributed to them.

The motions for summary judgment will be granted. Appropriate orders will be entered.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MARGARET SCHMERLING and MORTON SCHMERLING	:	**CIVIL ACTION**
v.	:	
DANEK MEDICAL, INC., et al.	:	**NO. 96-2749**

O R D E R

AND NOW, this day of September, 1999, upon consideration of the Motion for Summary Judgment of defendants Sofamor Danek Group, Inc., Sofamor, S.N.C., Sofamor, Inc. and Danek Medical, Inc. (the Sofamor/Danek defendants) (Doc. #50), the Motion for Summary Judgment of defendant Youngwood Medical Specialties, Inc. f/k/a National Medical Specialty, Inc., f/k/a Stuart Medical Specialty, Inc., f/k/a Stuart Medical, Inc., f/k/a Stuart Drug & Surgical Supply, Inc. (Doc. #53) and plaintiffs' responses thereto, consistent with the accompanying memorandum, **IT IS HEREBY ORDERED** that said Motions are **GRANTED** and accordingly **JUDGMENT IS ENTERED** in the above case for each of the moving defendants and against plaintiffs; and, as the claims against all other originally named defendants have been dismissed by prior stipulations and orders, the above case is closed.

BY THE COURT:

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JAY C. WALDMAN, J.